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EXAMINER	
LEE, SHUN K	

ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,457	CASPERSEN, CHRISTIAN	
	Examiner	Art Unit	
	Shun Lee	2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,11,12,14-16,23-25,27-29,36,37,40,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9,11,12,14-16,23-25,27-29,36,37,40,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 8, 9, and 14 are objected to because of the following informalities:

(a) claim 8, should probably be deleted;

(b) in claim 9, "claim 8, ... the predetermined curve" on lines 1-3 should probably be --claim 1, ... the non-linear curve--; and

(c) in claim 14, "a means for optical inspection of detected objects" on line 3 should probably be --said microscope--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 7-9, 11, 12, 14, 27, 29, 36, 37, 40, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349).

In regard to claim **1**, Reber *et al.* disclose (Fig. 1) an apparatus for detecting a property of marked object contained in a specimen, the apparatus comprising:

(a) a frame (is inherent in positioning mechanism 42; column 4, lines 17-28);

(b) a member (20) positioned on the frame and having a surface that is adapted to receive and hold the specimen (column 2, line 28 to column 3, line 7);

(c) at least a first light source is inherent for emitting at least a first light beam towards the specimen held by the member (20) since fluorescence (see *e.g.*, fluorescent members; column 3, lines 43-47) is defined[1] as the "emission of electromagnetic radiation, especially of visible light, stimulated in a substance by the absorption of incident radiation and persisting only as long as the stimulating radiation is continued";

(d) at least a detector (38) for detecting a light (*i.e.*, fluorescence) emitted from the marked objects (*i.e.*, fluorescent members; column 3, lines 43-47) upon interaction with the first light beam;

(e) scanning means (42) for scanning the specimen in relation to the detector (38) along a non-linear curve (*e.g.*, spiral 152 in Fig. 12), wherein the scanning means comprises means (*i.e.*, rotary positioning mechanism; column 4, lines 17-28; column 9, lines 37-40) for rotating the member and means (*i.e.*, translational positioning mechanism; column 4, lines 17-28; column 9, lines 37-40) for displacing the member, so as to detect the property of the marked objects in the entire specimen, the means for rotating and the means for displacing being simultaneously directly connected to the member (*i.e.*, a rotary positioning mechanism such as a spindle or a turntable, a translational positioning mechanism such as a conveyor, and/or a multiple degree of freedom positioning mechanism such as a robotic arm; column 4, lines 17-28), the member being simultaneously rotatable and displaceable (*i.e.*, the step of positioning at least one of the device

[1] The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by

20 and the detector 38 can include translating the device 20, rotating the device 20, translating the detector 38, and/or rotating the detector 38; column 9, lines 37-40); and

(f) scanning control means (*e.g.*, processor 36) for controlling the scanning means (42) for scanning the specimen along the non-linear curve (column 5, lines 1-9).

While Reber *et al.* also disclose (column 3, line 56 to column 4, line 10) to provide an apparatus comprising a detector 38 and (column 5, lines 1-9) that the positioning mechanisms are operated to collect data in a sequential manner from sites along annular (*e.g.*, circular 140 in Fig. 11) or spiral (*e.g.*, spiral 152 in Fig. 12) tracks (column 3, lines 5-7), the apparatus of Reber *et al.* lacks that the scanning control means is adapted to place a microscope at the position of the marked objects for optical inspection of the marked objects with means for retrieving position signals provided by the scanning control means from a storage means wherein the position signals stored in the storage means correspond to marked object detector signals stored in the storage means and that the first light source and the detector are arranged so that a part of a light beam path from the first light source to the specimen is co-axial with a part of the light emitted from the marked objects with the member displaced along a radius of the member rotation. First it should be noted that a spiral track is generated by relative translation along a radius of the rotary movement. Further, Gordon teaches (column 5, lines 28-31 and 64-67; column 8, lines 15-56; Fig. 1) a light beam path from a light source (8) to disc (1) that is co-extensive with a part of the light from the disc (1) to a

detector (11) wherein the detected signal data are transferred to a computer via a means for sampling and digitizing the signals and that the detected object positions stored in a storage means are retrieved and used by a scanning means to position a means for optical inspection of detected objects (*i.e.*, "look again at specific region of interest"; column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27). Virtanen teaches (column 48, lines 41-48) that with proper software, optical disk readers are scanning confocal laser microscopes which allow the study of the detailed structure of biological and other specimens. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a conventional epifluorescence microscope (having a conventional optical arrangement wherein a light beam path from a light source to specimen is co-extensive with a part of the fluorescence emitted from the specimen) and conventional means for sampling and digitizing detector and position signals in the apparatus of Reber *et al.*, in order to obtain data from measurements of specimens along annular or spiral tracks by relative translation along a rotational radius suitable for storage and processing on a conventional computer with the capability to look again at specific regions of interest (*e.g.*, any desired target object).

In regard to claim **29**, the method steps are implicit for the modified apparatus of Reber *et al.* since the structure is the same as the applicant's apparatus of claim 1.

In regard to claim **7** which is dependent on claim 1, Reber *et al.* also disclose (column 4, lines 17-28) that the member is positioned for rotation about an axis on the

frame and wherein the means for rotating the member rotates the member about the axis.

In regard to claims **8** and **9** which are dependent on claim 1, Reber *et al.* also disclose (column 5, lines 1-9) scanning control means (*e.g.*, processor 36) controlling the scanning means for scanning the specimen along a predetermined curve and that the scanning control means are adapted to control the scanning means in such a way that the predetermined curve is a substantially circular curve (*e.g.*, circular 140 in Fig. 11).

In regard to claim **11** (which is dependent on claim 10) and claim **37** (which is dependent on claim 36), while Reber *et al.* also disclose (column 3, lines 56-60; column 4, lines 4-10) a CD-ROM or DVD reader which provides signals for processing by a processor such as a computer (column 5, lines 1-22), the apparatus of Reber *et al.* lacks an explicit description of means for sampling and digitizing the detector signals and the position signals. Gordon teaches (column 8, lines 15-56) to transfer detected signal data to a computer via a means for sampling and digitizing the signals. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a means for sampling and digitizing the detector signals and the position signals in the apparatus of Reber *et al.*, in order to convert the data to a form suitable for processing by a computer.

In regard to claim **12** which is dependent on claim 1, Reber *et al.* also disclose (column 5, lines 1-22) signal processing means (*e.g.*, processor 36) operatively

connected to the detector (38) to detect a presence of an object based on the detector signals.

In regard to claim **14** which is dependent on claim 1, the apparatus of Reber *et al.* lacks that the detected object positions stored in the storage means are retrieved and used by said scanning means to position a means for optical inspection of detected objects. Gordon teaches (column 5, lines 58-62; column 6, lines 4-10 and 19-32; column 7, line 55 to column 8, line 27) that the detected object positions stored in the storage means are retrieved and used by said scanning means to position a means for optical inspection of detected objects (*i.e.*, "look again at specific region of interest"; column 6, lines 4-10). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to position an optical inspection means (*e.g.*, CD-ROM reader) in the apparatus of Reber *et al.* using the scanning means and retrieved stored detected object positions, in order to look again at specific regions of interest (*e.g.*, any desired target object).

In regard to claim **27** which is dependent on claim 1, while Reber *et al.* also disclose (column 3, lines 56-60; column 4, lines 4-10) a CD-ROM or DVD reader, the apparatus of Reber *et al.* lacks an explicit description that the CD-ROM or DVD reader comprises a coherent light source. However, CD-ROM (*i.e.*, compact discs) readers are well known in the art. For example, Gordon teaches (column 5, lines 28-31 and 64-67) that a conventional compact disc reader comprises a coherent light source. Therefore it would have been obvious to one having ordinary skill in the art at the time of the

invention that the detector (*e.g.*, a CD-ROM reader) in the apparatus of Reber *et al.* comprises a coherent light source.

In regard to claim **36** (which is dependent on claim 29), Reber *et al.* also disclose (column 5, lines 58-62) storage means (*e.g.*, memory 49 or device 20) for storage of detector signals (related to the detected property) provided by the detector (38) and corresponding position signals (related to the current position of the member) provided by the scanning control means.

In regard to claim **40** which is dependent on claim 1, Reber *et al.* also disclose (column 3, lines 39-47) that the marked objects are marked with a fluorescent stain.

In regard to claim **44** which is dependent on claim 1, the apparatus of Reber *et al.* lacks that the detector comprises a CCD device. Gordon teaches (column 10, lines 7-19) to provide a CCD device for scanning a disc in order to obtain higher speed and higher resolution. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a CCD device as the detector in the apparatus of Reber *et al.*, in order to obtain higher speed and higher resolution.

4. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349) as applied to claim 1 above, and further in view of Demers (WO 98/12559).

In regard to claims **15** and **16** which are dependent on claim 1, while Reber *et al.* also disclose (column 7, lines 59-62) a member such as a standard CD-ROM to receive

and hold the specimen, the modified apparatus of Reber *et al.* lacks that the specimen has an area larger than 500 mm^2 (*e.g.*, larger than 8000 mm^2). However, standard CD-ROMs (*i.e.*, compact discs) are well known in the art. For example, Demers teaches (pg. 5, third paragraph) that a compact disc is a 5.5 inch disc. A ~15328 mm^2 area has a diameter of ~140 mm (5.5 inch). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the ~15328 mm^2 area (*i.e.*, standard CD-ROM sized) member in the modified apparatus of Reber *et al.* is capable of receiving and holding specimens of ~15328 mm^2 area or less (*e.g.*, larger than 500 mm^2 or 8000 mm^2).

5. Claims 23-25, 28, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reber *et al.* (US 6,110,748) in view of Gordon (US 5,892,577) and Virtanen (US 6342349) as applied to claims 1 and 40 above, and further in view of Ekins *et al.* (Multianalyte microspot immunoassay-microanalytical "compact disk" of the future, Clinical Chemistry, Vol. 37, no. 11 (1991), pp. 1955-1967).

In regard to claims **23-25** which are dependent on claim 1, the modified apparatus of Reber *et al.* lacks that a mask is inserted in the optical path between the specimen and the detector, wherein the mask comprises at least one transparent aperture having a substantially rectangular shape with at least one dimension of the aperture, as projected on the specimen, between 0.75 and 2 times the dimensions of objects to be detected. Ekins *et al.* teach (left column on pg. 1964) that the highest signal/noise ratio is observed when the instrument field of view is restricted to a microspot area. Therefore it would have been obvious to one having ordinary skill in the

art at the time of the invention to provide an aperture in the modified apparatus of Reber *et al.* to restrict the field of view to substantially a microspot area (*i.e.*, matching size and shape), in order to detect fluorescent members with a desired signal/noise ratio.

In regard to claim **28** which is dependent on claim 1, the modified apparatus of Reber *et al.* lacks that the first light beam is adapted provide a light spot having a diameter between 20-150 μm on the specimen. Ekins *et al.* teach (left column on pg. 1963) that as the area decreases, the signal/noise ratio increases and approaches a maximum value of 60 as the area falls below 0.01 mm^2. A 0.01 mm^2 area has a diameter of 112 μm. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a light spot having a diameter between 20-150 μm (*e.g.*, 112 μm) on the specimen in the modified apparatus of Reber *et al.*, in order to detect fluorescent members with a desired signal/noise ratio.

In regard to claim **45** which is dependent on claim 40, while Reber *et al.* also disclose (column 3, lines 39-47) the detection of fluorescent members, the modified apparatus of Reber *et al.* lacks that the fluorescent marker is Fluorescein. However, fluorescent markers such as fluorescein are well known in the art. For example, Ekins *et al.* teach (left column on pg. 1965) that fluorescein fluorescent markers (*e.g.*, FITC) are commercially available. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention that the fluorescent members in the modified apparatus of Reber *et al.* is a known fluorescent member (*e.g.*, Fluorescein).

Response to Arguments

6. Applicant's arguments filed 17 June 2005 have been fully considered but they are not persuasive.

Applicant argues (first paragraph on pg. 10 of remarks filed 17 June 2005) that Reber *et al.* do not teach that the spindle/turntable and the conveyor are simultaneously directly connected to the device 20 since the device 20 can only be either on a spindle/turntable or on a conveyor. Examiner respectfully disagrees. Reber *et al.* state (column 4, lines 18-24) that "Depending on the form of the device **20** and the arrangement of the machine-readable data and the molecular receptors, the positioning mechanism **34** can include a rotary positioning mechanism such as a spindle or a turntable, a translational positioning mechanism such as a conveyor, and/or a multiple degree of freedom positioning mechanism such as a robotic arm". The key phrase is "and/or". Thus Reber *et al.* expressly teach a positioning mechanism 34 directly connected to the device 20 and comprising both a translational positioning mechanism and a rotary positioning mechanism.

Applicant argues (last paragraph on pg. 10 to second paragraph on pg. 11 of remarks filed 17 June 2005) that Reber *et al.* fail to teach that the member is simultaneously rotatable and displaceable along a radius of the rotation of the member. Examiner respectfully disagrees. Reber *et al.* state (column 9, lines 37-40) that "The step of positioning at least one of the device **20** and the detector **38** can include translating the device **20**, rotating the device **20**, translating the detector **38**, and/or

rotating the detector **38**". The key phrase is "and/or". Thus Reber *et al.* expressly teach that the step of positioning comprises both translating and rotating the device 20.

Applicant argues (last two paragraphs on pg. 11 of remarks filed 17 June 2005) that the combination of cited references does not suggest a microscope since the microscope of Virtanen is non-enabled since Virtanen does not discloses how proper software should be constructed nor are there any references disclosing how the skilled person should solve the problem of designing proper software. Examiner respectfully disagrees. The amount of information disclosed in a patent is not an indication of enablement or non-enablement. On the contrary, the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art (see MPEP § 2164.03). Thus applicant's argument that does not discloses how proper software should be constructed nor provide any references disclosing how the skilled person should solve the problem of designing proper software does not lead to a conclusion that Virtanen is non-enabled. Therefore, applicant's arguments are not persuasive.

Applicant argues (last three paragraphs on pg. 12 of remarks filed 17 June 2005) that the combination of cited references does not suggest the elements recited in the independent claims. Examiner respectfully disagrees for the reasons discussed above.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shun Lee whose telephone number is (571) 272-2439. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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